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HOWREY LLP
C/O IP DOCKETING DEPARTMENT
2941 FAIRVIEW PARK DRIVE, SUITE 200
FALLS CHURCH, VA 22042-7195

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ERIC T. KOOL

Appeal 2008-2113[1]
Application 10/604,400
Technology Center 1600

Decided: June 11, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composition containing a compound that has a fluorophore group and a fluorescence quenching leaving group. The Examiner made two anticipation rejections. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] Heard May 20, 2008.

We affirm one of the rejections, and reverse the other.[2] Because we find that the reference from the affirmed rejection renders unpatentable claims that the Examiner had not rejected, we also enter new grounds of rejection.

STATEMENT OF THE CASE

The Specification discloses oligonucleotide compounds that "contain[] a fluorophore[] and a 5' quenching leaving group. Upon ligation with another molecule in intermolecular fashion, or with itself in intramolecular fashion, the quenching leaving group is displaced, and the fluorophore is no longer quenched. The change in fluorescent properties of the molecule can be detected, providing a quantitative and qualitative assay of ligation" (Spec. [0031]).

Claims 1-14 stand rejected and are on appeal (*see* Advisory Action 1 (March 13, 2007)).[3] Claim 1, the only appealed independent claim, is representative and reads as follows:

> 1. A composition comprising a fluorophore compound, the fluorophore compound comprising a fluorophore group and a fluorescence quenching leaving group.

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[2] In this decision we consider only those arguments actually made by Appellant. Arguments that Appellant could have made but chose not to make in the Briefs have not been considered and are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(vii).

[3] Claim 15 stands objected to by the Examiner (Advisory Action 1 (March 13, 2007)). Appellant requests the Board to reverse this objection (*see* Br. 6, 22). However, claim objections are not appealable. *See* MPEP § 706.01 ("rejection" appealable to Board; "objection" of the type applied to claim 15 reviewed by way of petition to PTO Director). Thus, "the Board will not hear or decide issues pertaining to objections and formal matters which are not properly before the Board. These formal matters should not be combined in appeals to the Board." *Id.*

The Examiner applies the following documents in rejecting the claims:

Livak, K.J. et al., *Oligonucleotides with Fluorescent Dyes at Opposite Ends Provide a Quenched Probe System Useful for Detecting PCR Product and Nucleic Acid Hybridization*, 4 PCR Methods and Applications 357-362 (June 1995).

Xu, Y. et al., *Nonenzymatic autoligation in direct three-color detection of RNA and DNA point mutations*, 19 Nature Biotechnology 148-152 (February 2001).

The following rejections are before us for review:

Claims 1-8, 10, 11, and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Livak (Ans. 3-4).

Claims 1, 5-7, 9, and 12-14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Xu (Ans. 4-5).

ANTICIPATION -- LIVAK

ISSUE

The Examiner cites Livak as disclosing "a nucleic acid probe comprising a fluorophore FAM and a quencher TAMRA" (Ans. 4). The Examiner contends that the probe's TAMRA moiety, a rhodamine-containing group, meets claim 1's limitation that the quenching group must also being a leaving group because "[i]n general, for every chemical bond connecting two chemical groups there is somewhere a nucleophilic group, which will attack it under proper chemical conditions" (*id.* at 6). The Examiner further contends that the Specification's general definition of "leaving group" only "requires that the 'leaving group' leaves at some point in time (in principle, in might be years later). Therefore, in absence of any

particular chemical structure claimed this limitation reads on any fluorescent dye with acceptor properties" (*id.*).

Appellant contends that in view of the definition and examples provided in the Specification, the "the rhodamine quencher dye taught by Livak is not a 'leaving group' as defined in the claimed invention" (*see* Br. 18).

Appellant states that "claims 1-8, 10, 11 and 14 on appeal stand or fall together" (*id.* at 17). We select claim 1 as representative of the rejected claims. *See* 37 C.F.R. § 41.37(c)(1)(vii). The issue with respect to this rejection, therefore, is whether the Examiner erred in finding that Livak meets all of the limitations recited in claim 1.

FINDINGS OF FACT ("FF")

1. Claim 1 recites a composition that contains a fluorophore compound. The fluorophore compound must have a fluorophore group and a fluorescence quenching group. The fluorescence quenching group must be a leaving group.

2. Livak discloses a probe for detecting the accumulation of PCR-amplified nucleic acid sequences (Livak 357 (abstract)). Livak's probe "is an oligonucleotide with both a reporter fluorescent dye and a quencher dye attached" (*id.*). When the probe sequence is amplified, the 5' → 3' nucleolytic activity of the *Taq* polymerase cleaves the probe sequence, thereby separating the quenching group from the fluorescent reporter dye, resulting in detectable fluorescence (*id.*; *see also* 358 (Figure 1)).

3. Livak's probe consists of an oligonucleotide with the fluorescent moiety 6-carboxyfluorescein ("6-FAM") attached to the 5' end of the

oligonucleotide, and the fluorescence quenching moiety 6-carboxytetramethylrhodamine succinimidyl ester ("TAMRA NHS ester") attached to the 3' end using a "3'-blocking phosphate" (*see id.* at 357-58).

4. Regarding leaving groups, the Specification states:

> Examples of quenching leaving groups are shown in Figure 2 (note that in the figure they are attached to the 5' carbon of a nucleoside, but they can be attached to any atom that is reactive with a nucleophile. The leaving groups in the figure include the sulfur and the three oxygen atoms attached to it, as well as the carbon chain attached to sulfur. Leaving groups in general are defined by (a) their ability to activate an atom (to which they are attached) for attack by a nucleophile group and (b) to leave (either simultaneously or subsequently) when the nucleophile does attack.

(Spec. [0035].)[4]

5. The Specification states that one embodiment of the invention is "a quencher labeled nucleic acid molecule" in which the "quenching group is preferably covalently attached to the 5' hydroxyl group of the nucleic acid molecule" (Spec. [0039]). The Specification states that, "[a]lternatively, the 3' hydroxyl can be attached to a quenching leaving group" (*id.* at [0041]).

PRINCIPLES OF LAW

It is well settled that "[t]o anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

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[4] The Appeal Brief repeatedly refers to this paragraph as paragraph [0037], apparently referring to the numbering in the published application. *See, e.g.,* Br. 15, 18). We will, however, refer to the paragraph numbering used in the Specification present in the official electronic filewrapper.

It is also well settled that "[t]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims." *Id.* at 1478 (quoting *In re Swinehart,* 439 F.2d 210, 212 (CCPA 1971)). However, as stated in *Schreiber*, 128 F.3d at 1478 (quoting *Swinehart*, 439 F.2d at 213):

> [W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

With respect to claim language, during examination, the PTO must interpret terms in a claim using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

ANALYSIS

We agree with the Examiner that Livak's probe meets all of the limitations in claim 1. Livak's probe has a fluorescent moiety, 6-FAM, and a fluorescence quenching moiety, TAMRA (*see* FF 2, 3). Thus, Livak's probe meets the limitation of claim 1 requiring the compound to have a fluorophore group and a fluorescence quenching group.

Moreover, Livak's quenching moiety is attached to the 3'-end of the oligonucleotide probe (FF 3). Appellant's Specification discloses that, in general, leaving groups are suitably attached to any atom that is reactive

with a nucleophile (FF 4), and in particular, that the 3'-hydroxy group of an oligonucleotide is a suitable location for a quenching leaving group (FF 5).

Thus, because claim 1 does not limit the leaving group to any particular structure, or any particular reaction conditions or attacking nucleophile, and because Livak's TAMRA is attached to a position on an oligonucleotide disclosed in the Specification as being susceptible to nucleophilic attack, we also agree with the Examiner that it was reasonable to conclude that Livak's fluorescent quenching moiety is capable of functioning as a leaving group.

When a reasonable basis exists for concluding that a prior art product inherently meets a functional limitation recited in a product claim, Appellant bears the burden of establishing non-anticipation. *See In re Schreiber*, 128 F.3d at 1478.

Appellant contends that because the Examiner interpreted the term "fluorescence quenching leaving group" in a manner inconsistent with the Specification, the Examiner interpreted that term too broadly (*see* Br. 14-17). Specifically, Appellant contends that "even when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents" (*id.* at 13 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc); *Vitronics Corp. v. Conceptronic lnc.*, 90 F.3d 1576 (Fed. Cir. 1996); *Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328 (Fed. Cir. 2004)). Thus, Appellant reasons, the Specification's "descriptions and examples clearly imply that the fluorescence quenching leaving group *in the context of the instant*

application is not any fluorescence quenching group; rather, it is a group that is both a quencher and a leaving group as a single entity" (Br. 16).

Appellant's argument does not persuade us that the Examiner was unreasonable in concluding that claim 1's recitation "fluorescence quenching leaving group" encompasses Livak's quenching group. Specifically, "while 'the specification [should be used] to interpret the meaning of a claim,' courts must not 'import[ ] limitations from the specification into the claim.' . . . [I]t is improper to 'confin[e] the claims to th[e] embodiments' found in the specification . . . ." *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.,* 415 F.3d 1303, 1323 (citations omitted, bracketed text in internal quotes in original); *see also Sjolund v. Musland*, 847 F.2d 1573, 1581 (Fed. Cir. 1988) ("[W]hile it is true that claims are to be interpreted *in light of* the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims."); *In re Bigio,* 381 F.3d 1320, 1325 (Fed Cir. 2004) ("[A]bsent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaims the broader definition.").

Thus, even if claim 1 is interpreted as being limited to a compound whose quencher and leaving group are a single entity, as Appellant urges, claim 1 still does not limit that single entity to any particular chemical moiety; nor does claim 1 place any limit on the reaction conditions or attacking nucleophile that must cause the group to leave. Because claim 1 has essentially no limitation on the quenching group's structure, or the conditions that must cause the quenching group to leave, and because

Livak's TAMRA quencher is attached to a position on an oligonucleotide disclosed in the Specification as being susceptible to nucleophilic attack (*see* FF 3, 5), we agree with the Examiner that it was reasonable to conclude that claim 1 encompasses Livak's compound.

Appellant argues that Livak's rhodamine quencher "is not a 'leaving group' as defined in the claimed invention" because Livak's quencher "does not activate the atom (to which it is attached) for attack by a nucleophile group" (Br. 18 (citing Specification [0035]). We are not persuaded by this argument.

It is well settled that argument by counsel cannot take the place of evidence. *In re Cole*, 326 F.2d 769, 773, (CCPA 1964); *In re Geisler*, 116 F.3d 1465, 1471 (Fed. Cir. 1997). Appellant has not provided, nor do we see, any evidence showing that Livak's TAMRA group would fail to activate its attached atom for nucleophilic attack under the appropriate conditions. Rather, given the fact that claim 1 encompasses groups that leave under any reaction conditions, and given the TAMRA group's attachment at a location on an oligonucleotide disclosed in Appellant's Specification as being susceptible to nucleophilic attack (*see* FF 3, 5), we agree with the Examiner that it was reasonable to conclude that Livak's quencher would be a leaving group given an appropriate set of conditions.

Appellant argues that it was not reasonable for the Examiner to conclude that Livak's quencher was a leaving group because it is Livak's reporter dye, rather than the quencher, that leaves the oligonucleotide when enzymatic cleavage occurs, the quencher remaining attached to the probe (Br. 18-19). Appellant argues that it was not reasonable for the Examiner to conclude that any fluorescent quenching group would also inherently be a

leaving group (*id.* at 18), given the disclosures of Livak, Moran,[5] and Bichenkova,[6] which disclose nucleic acid detection with fluorescent labels that do not act as leaving groups (*id.* at 16).

We are not persuaded by these arguments. Claim 1 does not limit the fluorescence quenching leaving group to a moiety that leaves only under a specific set of reaction conditions. Rather, claim 1 encompasses quencher moieties that leave under any reaction conditions. Thus, while the fluorescent moieties of Livak, Moran, and Bichenkova may remain attached to oligonucleotides under the limited set of conditions disclosed in those references, that fact does not demonstrate that Livak's quencher moiety would fail to leave the oligonucleotide molecule under any of the wide variety of reaction conditions encompassed by claim 1.

In sum, for the reasons discussed above, we agree with the Examiner that it was reasonable to find that Livak anticipates claim 1. Because Appellant has failed to meet the burden of showing that the Examiner's reasonable finding of anticipation was erroneous, we affirm the Examiner's rejection of claim 1 as anticipated by Livak. Because claims 2-8, 10, 11, and 14 were not argued separately, they fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(vii).

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[5] Moran, N. et al., *Detection of a single DNA base-pair mismatch using an anthracene- tagged fluorescent probe*, Chem. Commun., 2006, 5003-5005 (2006).

[6] Bichenkova, E.V. et al., *Detection of nucleic acids in situ: novel oligonucleotide analogues for target-assembled DNA-mounted exciplexes*, 5 Org. Biomol. Chem. 1039-1051 (2007).

ANTICIPATION -- XU

ISSUE

Claims 1, 5-7, 9 and 12-14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Xu (Ans. 4-5).

The Examiner contends that Xu anticipates claim 1 because it discloses "a fluorophore compound consisting of two nucleic acid probe pairs, where the 13 bp probe contains a FAM fluorophore and the 7 bp probe contains either a ROX acceptor (= quencher) or a HEX acceptor (= quencher)" (Ans. 4).

Appellant contends that "Xu does not teach or suggest a fluorescence quenching leaving group for their 13-mer or 7-mer probe, let alone a fluorophore compound as a single molecule comprising a fluorophore group and a fluorescence quenching leaving group, as claimed in the instant application" (Br. 20).

The issue with respect to this rejection, then, is whether the Examiner erred in concluding that claim 1's "fluorophore compound" encompasses Xu's probe pairs.

FINDINGS OF FACT

6. Xu discloses that adjacently hybridizing probes can become nonenzymatically ligated (Xu 148). Because the ligation reaction depends on specific hybridization, the presence of a ligated product can be used to detect point mutations in nucleic acid sequences (*id.*).

7. In the diagnostic methods, Xu uses three distinct probes: (a) a "universal probe" consisting of an oligosaccharide labeled with 5-carboxyfluorescein (FAM), which is used as the fluorescence resonance energy transfer (FRET) donor; (b) a "WT" probe consisting of an

oligosaccharide having a sequence complementary to the wild-type form of the gene to be detected, the WT probe being labeled with hexachlorofluorescein (HEX), a FRET acceptor; and (c) a "MUT" probe consisting of an oligosaccharide having a sequence complementary to the mutated form of the detected gene, the MUT probe being labeled with rhodamine (ROX), a second FRET acceptor (Xu 150, *especially* Figure 3).

8. When hybridized with a target sequence, if either the WT or MUT probe hybridizes adjacent to the universal probe and becomes ligated to it, the label on the WT or MUT probe will quench the universal probe's FAM dye and fluoresce in its respective color (Xu 150).

ANALYSIS

We agree with Appellant that the Examiner erred in finding that Xu's probe compositions anticipate claim 1.

Claim 1 requires its composition to contain a fluorophore compound that has a fluorophore group *and* a fluorescence quenching group. None of Xu's probes has both a fluorophore group and a fluorescence quenching group. Rather, Xu's probes are compounds that have *either* a fluorophore group *or* a fluorescence quenching group (*see* FF 7-8).

Because Xu's probes do not meet all of the limitations required of claim 1's fluorophore compound, we agree with Appellant that Xu does not anticipate claim 1, or its dependent claims 5-7, 9, and 12-14.

The Examiner argues that because the Specification does not define the term "fluorophore compound," it is proper to interpret it as "either [a] unimolecular or multimolecular entity" (Ans. 3). The Examiner urges that this interpretation of the word "compound" is consistent with the understanding of one skilled in the art because, "for example, 'a protein'

does not imply a single molecule, since a large proportion of proteins are multimolecular. Further, the specification does not explicitly exclude the possibility that the compound contains more than one molecule" (*id.* at 5).

We are not persuaded by this argument. While claim terms must be given their broadest reasonable interpretation consistent with the Specification, that interpretation must also be consistent with the understanding of a person of ordinary skill in the art. *See In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). In the instant case, we do not agree with the Examiner that a person of ordinary skill would interpret the term "compound" in claim 1 to encompass Xu's compositions having two separate non-covalently linked probe molecules, as urged by the Examiner.

Therefore, because we agree with Appellant that Xu's probes do not meet all of the limitations required of claim 1's fluorophore compound, we reverse the Examiner's anticipation rejection of claim 1, and its dependent claims 5-7, 9, and 12-14.

NEW GROUND OF REJECTION -- ANTICIPATION

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection: Claim 12 is rejected under 35 U.S.C. § 102(b) as being anticipated by Livak.

Claim 12 recites "[t]he composition of claim 1, wherein the fluorophore compound further comprises a nucleophilic group." The Specification states:

> In general, nucleophilic groups (contemplated in this Invention) include phosphorothioate and phosphoroselenoate groups, thiol and thiolate groups, hydroxy and oxyanion groups, *amines*, hydroxylamines, hydrazines, hydrazides, phosphines, thioacids and their conjugate bases, selenols and selenoates. *These can be attached to any molecule or object.*

(Spec. [0036] (emphasis added).)

As discussed above, we agree with the Examiner that the oligonucleotide probes of Livak anticipate claim 1. Because the purines and pyrimidines in Livak's oligonucleotide probes contain amine groups, and because amines are disclosed in Appellant's specification as being suitable nucleophiles, Livak also anticipates claim 12.

NEW GROUND OF REJECTION -- OBVIOUSNESS

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection: Claim 9 is rejected under 35 U.S.C. § 103(a)[7] as being obvious in view of Livak.

Claim 9 recites "[t]he composition of claim 6, wherein the quenching leaving group is attached to the 5' hydroxyl group of the nucleic acid."

Claim 6 recites "[t]he composition of claim 1, wherein the fluorophore compound is a nucleic acid."

Recently addressing the question of obviousness, the Supreme Court reaffirmed that under the controlling inquiry, "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *KSR Int' l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734

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[7] 35 U.S.C. § 103(a) states:
A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(2007) (quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)).

Emphasizing a flexible approach to the obviousness inquiry, the Supreme Court reasoned that the analysis under 35 U.S.C. § 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 1741. The Court further advised that "[a] person of ordinary skill is . . . a person of ordinary creativity, not an automaton." *Id.* at 1742.

As discussed above, we agree with the Examiner that Livak anticipates claims 1 and 6. As also discussed above, Livak discloses oligonucleotide probes having a fluorophore group at the 5' end of the molecule and a fluorescence quenching leaving group at the 3' end of the molecule (FF 3).

Livak therefore differs from claim 9 in that Livak's fluorescence quenching leaving group is attached to the 3' end of the oligonucleotide rather than the 5' hydroxyl as recited in claim 9. However, Livak discloses that, based on the results of their experiments, "oligonucleotides with reporter and quencher dyes attached at opposite ends can be used as homogeneous hybridization probes" (Livak 357 (abstract); *see also* Livak 362 ("The results presented here demonstrate that the simple addition of a reporter dye to one end of an oligonucleotide and a quencher dye to the other end generates a fluorogenic probe that can detect hybridization or PCR amplification.")).

Thus, one of ordinary skill in the art, being a person of ordinary creativity and common sense, *see KSR,* 127 S. Ct. at 1742-43, and being

advised by Livak of the usefulness of probes with reporter and quencher dyes at opposite ends of the molecule, would have reasonably inferred from Livak that probes having a quenching leaving group at the 5' hydroxyl end and a reporter moiety at the 3' hydroxyl would be equivalently useful to the exemplified probes for detecting hybridization or PCR amplification. That is, in view of Livak's general disclosure of the usefulness of probes with reporter and quencher moieties at the molecules' ends, one of ordinary skill would have reasoned that a probe having the quencher and reporter moieties at either end of the molecule would be useful for detecting hybridization or PCR amplification.

Because a person of ordinary skill would therefore have recognized the usefulness of probe molecules having a quenching leaving group at the 5' hydroxyl position and a reporter dye at the 3' end, we find that the ordinary artisan would have been prompted to prepare such a molecule. We therefore conclude that claim 9 would have been obvious to a person of ordinary skill at the time the invention was made.

SUMMARY

We affirm the Examiner's rejection of claims 1-8, 10, 11, and 14 under 35 U.S.C. § 102(b) as being anticipated by Livak.

We reverse the Examiner's rejection of claims 1, 5-7, 9, and 12-14 under 35 U.S.C. § 102(b) as being anticipated by Xu.

We enter a new ground of rejection of claim 12 under 35 U.S.C. § 102(b) as anticipated by Livak. *See* 37 C.F.R. § 41.50(b).

We enter a new ground of rejection of claim 9 under 35 U.S.C. § 103(a) as being obvious over Livak. *See* 37 C.F.R. § 41.50(b).

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner . . . .
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record . . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART, 37 C.F.R. § 41.50(b)

Ssc:

HOWREY LLP
C/O IP DOCKETING DEPARTMENT
2941 FAIRVIEW PARK DRIVE, SUITE 200
FALLS CHURCH, VA 22042-7195